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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,272	06/23/2001	Fumiaki Katagiri	1360.003US2	5142

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EXAMINER
IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,272	KATAGIRI ET AL.	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I and SEQ ID NO: 4794 in the reply filed on 02/27/06 is acknowledged. The requirement is made Final.

Claims 1-33 and SEQ ID NO: 4794 are pending and are examined.

Claim Objections

Claims 3-5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The nucleotide sequences of claims 3- 5 are broader in scope than the nucleotide sequence of claims 1 and 2. Therefore, claims 3-5 fail to further limit parent claims 1 and 2.

Specification

The disclosure is objected to because of the following informalities: for example, page 23, lines 4-5; page 56, line 8; page 57, line 13; and the Table on pages 83-87 contain an embedded hyperlink directed to an Internet address. The use of hyperlinks and/or other form of browser- executable code are not permitted under USPTO current policy because the content of such links are subject to a change, resulting in the introduction of New Matter into the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser- executable code. See MPEP 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it is unclear as to whether the claim is drawn to a gene encoding a polypeptide or a promoter from that gene or both. Clarification is required to more clearly define the metes and bounds of the claim. Dependent claims 6-18 are included in the rejection.

Claim 3 is indefinite because "very high" is relative term lacking comparative basis. The specification fails to clearly define the phrase, thus one would not know the metes and bounds of the claim.

Claims 19-20 are indefinite because it is unclear as to whether the novelty of the claimed method is the use of a gene encoding a polypeptide or a promoter from that gene or both . Clarification is required to more clearly define the metes and bounds of the claim. Dependent claims 21-33 are included in the rejection.

Claim 32 is indefinite because "a product of a plant" is so broad in that the metes and bounds of the claim cannot be determined.

Claims 15 and 19 are indefinite because what is encompassed by "augmenting a plant genome" or "augmented" genome is unclear. The phrase is not clearly defined in

the specification and is not well known in the art. Clarification is required to more clearly define the metes and bounds of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to an isolated polynucleotide comprising a plant nucleotide sequence that alters transcription of an operably linked nucleic acid segment in plant cell after pathogen infection, wherein the plant nucleotide sequence is from gene encoding a polypeptide substantially similar to a polypeptide encoded by a gene comprising the promoter sequence of SEQ ID NO: 4794, the plant nucleotide sequence hybridizes to the complement of SEQ ID NO: 4794 under high and very high stringency conditions, or is 25 to 2000 nucleotides in length, and is from a monocot, dicot, or from a cereal plant. The claims are also drawn to an expression cassette comprising said polynucleotide operably linked to an open reading frame, host cell, and specific monocot and dicot plants transformed with said expression cassette. The claims are

also drawn to a method of altering a plant genome/phenotype with said expression cassette

Applicant teaches identification and isolation of number of promoters from plant genes that are responsive to particular pathogens. Applicant teaches that SEQ ID NO: 4794 (elected sequence) is from an uncharacterized rice gene whose expression is induced by pathogen infection. Applicant, therefore, asserts that SEQ ID NO: 4794 is a pathogen responsive promoter and can be used to alter transcription of an operably linked nucleic acid segment. Applicant, however, has provided no evidence that relates SEQ ID NO: 4794 to pathogen-responsive promoter activity. Applicant has not provided guidance regarding identification of the promoter region necessary for pathogen-responsive activity. No sequences or regions necessary for promoter activity are identified or evaluated.

The state of the art, as evidence by Kim et al (Plant Molecular Biology, vol. 24, pp. 105-117, 1994) teaches unpredictability inherent in the identification and function of promoters. Kim et al teach the extreme sensitivity of promoter regions and the failure of a promoter to function either constitutively or specifically when lacking oligonucleotide regions approximately 100 bp upstream of the transcription start site (page 106, paragraph bridging the columns; paragraph bridging pages 107 and 108; page 110, paragraph bridging the columns).

Therefore, given the lack of guidance as discussed supra; the unpredictability in the art with respect to promoter identification and function, lack of working examples in the specification, the claimed invention is not enabled.

Applicant is invited to provide evidence or data in the form declaration under 37 CFR 1.132 to support the pathogen responsive promoter activity by SEQ ID NO: 4794, to obviate the above rejection.

In the event that Applicant is able to overcome the above rejection, the enablement will still be limited to claims limited SEQ ID NO: 4794, for the reasons set forth below.

Applicant has not taught how and where to modify SEQ ID NO: 4794 to produce the promoter sequences of claims 1-3, and 5. Applicant has not taught a single variant of SEQ ID NO: 4794 having both the structural and functional property as recited in the claims. Applicant has not provided guidance for which 25 nucleotides of SEQ ID NO: 4794 has the ability to alter transcription of an operably linked nucleotide sequence after pathogen infection in a plant cell. One skilled in the art would not expect that every 25 nucleotides of SEQ ID NO: 4794 would possess promoter activity. Applicant has not taught which regions in SEQ ID NO: 4794 would tolerate modifications, so as nucleotide sequences that would hybridize to the complement of SEQ ID NO: 4794 under high or very high stringent conditions having the desired promoter activity could be obtained. One skilled in the art would have to test every 25 bases of SEQ ID NO: 4794 and multitude of sequences that hybridize thereto, to determine which would have the desired promoter activity. These tests are considered undue and extensive.

Benfey et al. (Science 1990, vol. 250, pages 959-966(V)) teach that subdomains of CaMV 35S can provide tissue-specific expression and that the subdomains of the promoter can vary depending on the location of a subdomain within the promoter (Table

1, page 963; Figure 1, page 960). Benfey et al further teach that particular combinations of subdomains showed different patterns of tissue-specific expression when introduced into different species of plants (Figure 4, page 963). See also, Keller et al (The Plant Cell, vol. 3, pp. 1051-1061, 1991) who teach unpredictability relating to modifications to promoters with specific activity promoters and the inability of modified promoters to provide the desired gene expressions in transgenic plants (see at least page 1053, Figure 2 and Table 1; and page 1056, Figure 4). Keller specifically teaches that vascular-specific expression is controlled by a complex set of positive and negative interactions between cis-acting regulatory regions, and teaches that any disturbance of these interactions results in non vascular-specific expression of the desired heterologous DNA (paragraph bridging 1057 and 1059). Therefore, modifications to promoters that retain its activity are unpredictable.

See *Amgen Inc. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021 and 1027 (Fed. Cir. 1991) at page 1021, where it is taught that a gene or a promoter is not reduced to practice until the inventor can define it by its "physical or chemical properties" (e.g. a DNA sequence) and page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Written Description

Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention does not meet the current written description requirements for the following reasons. Firstly, Applicant provided no evidence to support the promoter function by SEQ ID NO: 4794. Secondly, no regions necessary for promoter activity have been described. Thirdly, Applicant describes the plant nucleotide sequences of the claims either its hybridizing property or the gene it is isolated from. Fourthly, substantial variation in structures and function is expected among plant nucleic acids with 25 nucleotides of SEQ ID NO: 4794 in common. In addition, since Applicant has not described the promoter of the claims, expression cassette, transgenic plants, plant cells and a method of using said promoter are similarly not described. Therefore, the written description requirement is not satisfied.

See Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices). See, also *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997).

Applicant is invited to provide evidence in the form of 1.132 declaration to support the promoter activity of SEQ ID NO: 4794.

Remarks

No claim is allowed.

The claims are deemed free of the prior art of record.

Contact information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final

responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Mai
6/26/06

MEDINA A. IBRAHIM
PRIMARY EXAMINER